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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/538,396	03/29/2000	Pramod B. Mahajan	1116	6440

27310 7590 06/18/2002

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EXAMINER

IBRAHIM, MEDINA AHMED

ART UNIT PAPER NUMBER

1638

DATE MAILED: 06/18/2002

13

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary

Application No.

09/538,396

Applicant(s)

MAHAJAN ET AL.

Examiner

Medina Ibrahim

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 14 February 2002 and 16 April 2002.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-8 and 12-15 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-8 and 12-15 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
- Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved by the Examiner.
- If approved, corrected drawings are required in reply to this Office action.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. §§ 119 and 120

- 13) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application).
- a) ☐ The translation of the foreign language provisional application has been received.
- 15) ☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121.

Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 4) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 5) ☐ Notice of Informal Patent Application (PTO-152)
- 6) ☐ Other:

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DETAILED ACTION

The text of these sections of the Title 35, U.S. Code not included in this action can be found in a prior Office action.

Claims 2-8 and 12-15 are pending in this application and are under examination.

Claims 12-15 are newly added.

Applicants' response filed on 2/14/02 and the Supplemental response of 4/16/02 have been entered. It is noted that page 5 of the response of 2/14/02 is missing. Applicants are required to provide a substitute page in response to this Office action.

Withdrawn Rejections and Objections

The objection to the specification, the rejection under 112, 1st paragraph regarding written description for claims 2-8, and the art rejection to claims 2-8 have been withdrawn in view of Applicant's amendment to the claims in the responses filed 2/14/02 and 4/16/02. The utility rejection for the entire SEQ ID NO:1 encoding SEQ ID NO:2 has been withdrawn, as the Rad50 activity by SEQ ID NO:1 or 2 is an inherent property.

Claim Rejections - 35 USC § 101 Utility

Claims 2-8 remain rejected and new claims 12-15 are rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a credible asserted utility or a well established utility. This rejection is repeated for the same reasons as set forth in pages 3-7 of the Office action mailed on 11/19/01. Applicant's response of 2/14/02 has been considered but are not fully persuasive.

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Applicants' argument in pages 8-12 of the response of 4/16/02 regarding the substantial utility (Rad50 activity) of SEQ ID NO:1 encoding SEQ ID NO:2 is persuasive. However, Applicants' argument that utility is asserted for a polynucleotides having at least 85% sequence identity to SEQ ID NO:1, polynucleotides that hybridize thereto, complementary sequences, polynucleotides with at least 30 contiguous bases thereof, or a polynucleotide amplified from a *Zea mays* using primers which selectively hybridize under stringent conditions to loci within a polynucleotide of SEQ ID NO:1 and encoding a polypeptide having Rad50 activity is not persuasive because neither Applicants' specification nor the prior art teaches or provides guidance for how Rad50 activity can be assayed or tested. No working examples have been disclosed and no Rad50 activity have been confirmed for a polynucleotide having less than 100% of SEQ ID NO:1. Therefore, one skilled in the art would not be able to readily use a polynucleotide having less than 100% sequence identity to SEQ ID NO:1. Therefore, the utility rejection is made and maintained.

Claim Rejections - 35 USC § 112, 1st paragraph

Claims 2-8 remain rejected and new claims 12-15 are rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a credible utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention without undue experimentation. Applicants should note that no working examples have been disclosed for a polynucleotide having less than 100% of SEQ ID NO:3 and still having Rad50 activity.

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Written Description

New claim 13 is rejected under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. This rejection is repeated for the same reasons set forth in page 8 of the last Office action, for claim 1(c)-8 of record. Applicants' arguments in pages 12-13 of the response of 2/14/02 have been fully considered but are not persuasive.

Applicants assert that the polynucleotide of claim 13 has been described by chemical and physical characteristics which include the disclosure of SEQ ID NO:1, and the limitations that the polynucleotide is amplified from *Zea mays* a nucleic acid library and encode a polypeptide with Rad50 activity, and the primers must selectively hybridize under stringency conditions to loci within SEQ ID NO:1. Applicants assert that the guidance in the specification regarding amplification of polynucleotides, construction of a nucleic acid library, the disclosure of SEQ ID NO:1, and the defined parameters in the claim 13, would reasonably convey to one skilled in the art that Applicants had possession of the claimed invention. Therefore, it is requested that the rejection be withdrawn (p. 12-13 of the response). These arguments have been considered but are not found persuasive.

Applicants' assertions are incorrect because of the following reasons: firstly, the claim does not recite specific primers and specific stringency conditions for SEQ ID NO:1. Secondly,

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the claim requires that the primers selectively hybridize to loci **within** SEQ ID NO:1, but not to SEQ ID NO:1, therefore, the claim reads on a polynucleotide outside SEQ ID NO:1. Thirdly, even if the claimed polynucleotide encodes a polypeptide having Rad50 activity (an allelic variant of SEQ ID NO:1), the specific structure of the allelic variant is not known. The disclosure of SEQ ID NO:1 would not allow one skilled in the art to predictably determine what will be the structure of any allelic variant of SEQ ID NO:1 because there is no known correlation between structure and function of Rad50 DNA/protein. Therefore, a mere statement that the polynucleotide encodes Rad50 polypeptide does not rebut the Office's position. While Applicants are not required to disclose each and every member of the species encompassed by the claim or what is known in the prior art, the law requires that specification provides sufficient written description which would allow a skilled artisan to visualize or recognize the identity of the members of the genus. Therefore, absent further description, one skilled in the art would not recognize from the disclosure that Applicant was in possession of a polynucleotide amplified from a Zea mays using primers which selectively hybridize under stringent conditions to loci within a polynucleotide of SEQ ID NO:1.

The rejection is maintained.

Remarks

No claim is allowed.

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Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire **THREE MONTHS** from the mailing date of this action. In the event a first reply is filed within **TWO MONTHS** of the mailing date of this final action and the advisory action is not mailed until after the end of the **THREE-MONTH** shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than **SIX MONTHS** from the date of this final action.

1. Papers relating to this application may be submitted to Technology Sector 1 by facsimile transmission. Papers should be faxed to Crystal Mall 1, Art Unit 1638, using fax number (703) 308-4242. All Technology Sector 1 fax machines are available to receive transmissions 24 hrs/day, 7 days/wk. Please note that the faxing of such papers must conform with the Notice published in the Official Gazette, 1096 OG 30, (November 15, 1989).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Medina A. Ibrahim whose telephone number is (703) 306-5822. The Examiner can normally be reached Monday -Tuesday from 8:00AM to 4:00PM and Wednesday-Thursday from 9:00AM to 3:00 PM.

If attempts to reach the Examiner by telephone are unsuccessful, the Examiner's supervisor, Amy Nelson, can be reached at (703) 306-3218.

Any inquiry of a general nature or relating to the status of this application should be directed to the receptionist whose telephone number is (703) 308-0196.

June 16, 2002

mai

Phuong Bui
PHUONG T. BUI
PRIMARY EXAMINER 6/17/02